

17. (Amended) A medical laser delivery apparatus for treating an area of tissue comprising:
- a. a laser source having two or more lasers which are combined into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration;
- b. a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated;
- c. a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue.

23. (Amended) The medical laser delivery apparatus as claimed in claim 22 wherein at least one of the lasers is an erbium laser.

24. (Amended) The medical laser delivery apparatus as claimed in claim 22 wherein the erbium laser is an Er:YAG laser.

REMARKS

Applicants respectfully request further examination and reconsideration in view of the above amendment and the remarks set forth below. Prior to this amendment, Claims 1-14 and 17-24 were pending. Claims 15, 16 and 25-40 have previously been withdrawn in

response to the Examiner's Restriction Requirement. By the above amendment, Claims 1, 8-11, 17, 23 and 24 have been amended. Accordingly, Claims 1-14 and 17-24 are still pending.

Rejections Under 35 U.S.C. § 112

Within the Office Action, Claims 1-14 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The applicants respectfully traverse this rejection. Regarding Claims 1 and 2, it is stated within the Office Action that Claim 1 is incomplete in view of the recitation in Claim 2. Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated. Claim 2 adds a further limitation to the medical laser delivery apparatus of Claim 1, specifying that the medical laser delivery apparatus further comprises a laser delivery system coupled to the laser source for delivering the one or more pulses from the laser source to the area of tissue to be treated. As specified in these claims, the overall apparatus is a medical laser delivery apparatus. Claim 2 adds the further limitation that the medical laser delivery apparatus includes a laser delivery system coupled to the laser source for delivering the one or more pulses from the laser source to the area of tissue to be treated. Claim 3 further specifies that the laser delivery system comprises an articulated arm and one or more refocussing optics for refocussing the laser pulses as they travel through the arm. Accordingly, Claims 1 and 2 do particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Within the Office Action, it is further stated that in Claim 11 there is no antecedent basis in the specification for generating a coagulation depth in response to an ablative pulse. The applicants also respectfully traverse this rejection. Within the specification it is stated that "an ablation pulse from an erbium laser will create a coagulation region having a thickness of approximately 10 microns." [Specification, p. 6, lines 15-16] Accordingly, there is a clear antecedent within the specification of the present invention for this limitation. The Examiner is therefore requested to withdraw the rejections under 35 U.S.C. § 112.

Rejections Under 35 U.S.C. § 102

Within the Office Action, Claims 1, 2, 8 and 11 have been rejected under 35 U.S.C. § 102(e) as being clearly anticipated by U.S. Patent No. 5,662,643 to Kung et al. (hereinafter "Kung"). Kung teaches a laser welding system for surgically bonding tissue together. The surgical system of Kung includes a system input 10, a laser source 20, a delivery system 40 and a temperature feedback loop 30. [Kung, col. 2, lines 46-51] The system of Kung provides a coherent beam of light at a predetermined wavelength corresponding to a specific thickness of tissue at which substantially full absorption of the laser energy occurs, without allowing the temperature anywhere in the subject tissue to exceed a predetermined tissue temperature. [Kung, col. 2, lines 9-16] Kung does not teach a laser source which comprises two or more lasers which are combined into a single laser output to provide one or more non-ablative pulses.

In contrast to the teachings of Kung, the dual mode laser delivery system of the present invention includes a laser source with a short penetration depth and two or more lasers which are combined into a single laser output. A controllable ablation depth is achieved by the laser delivery system of the present invention by providing an appropriate series of pulses from the laser source having an energy and exposure time to achieve ablation of the exposed area of skin to the desired depth. Once ablation of the skin has been performed, a coagulation region to the desired coagulation depth is then generated within the remaining exposed layer of skin by preferably applying a series of one or more very short non-ablative laser pulses from the laser source at a high repetition rate in order to raise the temperature of the surface of the skin to a desired temperature for a period of time. The order of delivery of the ablation sequence and the coagulation sequence can also be reversed from that described if desired.

The laser source of the present invention includes two lasers 32 and 34 which generate laser beams 33 and 35, as illustrated in Figure 3. The two laser beams 33 and 35 are combined into a single laser output 37 by the galvanometer 36 which switches between the two laser outputs 33 and 35. The galvanometer 36 then provides the laser output 37 from the

laser source 31. As discussed above, Kung does not teach a laser source which comprises two or more lasers which are combined into a single laser output.

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The apparatus of Claim 1 comprises a laser source for generating a series of one or more non-ablative pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode. Claim 1 includes the further limitation that the laser source comprises two or more lasers which are combined into a single laser output to provide the one or more non-ablative pulses. As discussed above, Kung does not teach a laser source which comprises two or more lasers which are combined into a single laser output to provide the one or more non-ablative pulses. For at least these reasons, the independent Claim 1 is therefore allowable over the teachings of Kung.

Claims 2 and 8 are both dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Kung. Accordingly, Claims 2 and 8 are both also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source and a laser control system. Claim 11 specifies that the laser source has two or more lasers which are combined for generating a laser beam having a predetermined absorption length, wherein the absorption length forms a predetermined coagulation depth in response to an ablative laser pulse. As discussed above, Kung does not teach a laser source which comprises two or more lasers which are combined for generating a laser beam. For at least these reasons, the independent Claim 11 is therefore allowable over the teachings of Kung.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 3, 6-8, 11-14 and 17-19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin") and the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson"). Sklar teaches a method and apparatus for precision laser surgery. Sklar teaches a system which includes an imaging system providing a surgeon with abundant visual information on a video screen with indication of precisely where, a focused surgical laser beam is directed. [Sklar, Abstract] Sklar does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Further, Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue. Dew does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser

control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Accordingly, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

Claims 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Kung. Accordingly, Claims 3 and 6-8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to a medical laser comprising a laser source and a laser control system. Claim 11 specifies that the laser source has two or more lasers which are combined for generating a laser beam having a predetermined absorption length, wherein the absorption length forms a predetermined coagulation depth in response to an ablative laser pulse. The laser control system of Claim 11 is coupled for controlling the laser source for generating a plurality of coagulative laser pulses, such that each such coagulative laser pulse is delivered in sequence to a target area to form a coagulation region deeper than the predetermined coagulation depth. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 11 is therefore allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Kung and also the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue which comprises a laser source, a laser delivery system and a control system. Claim 17 specifies that the laser source has two or more lasers which are combined into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. Claim 17 further specifies that the control system is coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for into a single laser and a control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 17 is therefore allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 18 and 19 are both also allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 5, 9, 10 and 20-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Sklar in combination with Dew, Anderson, Belkin and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa"). Assa

teaches an apparatus for delivering energy within continuous outline. Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Kung and the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 4, 5, 9 and 10 are all also allowable as being dependent upon an allowable base claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 20-24 are all also allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (650) 833-0160 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

Dated: May 17, 2000

By: Jonathan O. Owens
Jonathan O. Owens
Reg. No.: 37,902

Attorneys for Applicant